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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,192	01/26/2007	Tomoyuki Igawa	14875-159US1 C1-A0315P-US	1989

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
01/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,192	IGAWA ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *13-33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/09/2007;10/31/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 04/07/2006, has been entered.

Claims 1-35 are pending.

Election/Restrictions

2. Applicant's election *without traverse* of Group I and species of magnesium ions and trehalose sugar in Response to Election / Restriction, filed 09/12/2008, is acknowledged.

Upon further consideration, search has been extended to sucrose and sorbital as the other species of sugar.

Claims 13-33 and 35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1-12 and 34 are currently under examination as they read on a solution of high concentration of IgM.

Priority

3. The domestic priority date for claims 1-12 and 34 is deemed the effective filing date of PCT/JP04/14935, i.e., 10/08/2004.

Applicant's claim for foreign priority is acknowledged. However, as there does not appear to be a certified English translation of Japanese priority application, 2003-351388; Examiner thus cannot determine whether the priority application provide sufficient written support for the present claims under examination.

Specification

4. Applicant is requested to review the application for spelling errors, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Objections

5. Claim 34 is objected to because it depend from a non-elected claim, claim 24. For examination purposes, the interpretation of claim 34 will encompass the limitation of claim 24. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 and 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high concentration" in the present claims is a relative term which renders the claims indefinite. The term "high concentration" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the concentration, i.e, what concentrations are high vs. low.

Applicant is invited to amend the claims to recited the exact concentration of the IgM such as that recited in claim 2 in place of “high concentration” to obviate this rejection.

Applicant is reminded that all amendment must point to a basis in the specification as-filed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombotz et al. (Pharm. Res. 1994, 11:624-632, cited on IDS, see entire document).

Gombotz et al. taught an aqueous solution of IgM wherein the concentration of IgM was higher than 1 mg/ml (page 625, right column, second paragraph; paragraph bridging pages 625-626; and page 626, right column, first full paragraph). The solution of IgM in PBS as taught by Gombotz (page 625, second paragraph and page 626, right column, first full paragraph) read on a pharmaceutical formulation because PBS is physiologically compatible and was pH7.4.

Given that the prior art taught a solution of a purified human monoclonal IgM antibody, it read on a solution that "does not intrinsically comprise human-derived protein other than IgM" and a solution that "does not intrinsically comprise proteins other than IgM. It is noted that the recitation of "*other than IgM*" does not exclude the IgM to be human-derived in the broadest reasonable interpretation of the claim in light of the specification.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 5-8 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz et al. (Pharm. Res. 1994, 11:624-632, cited on IDS) in view of Arvinte et al. (WO 02/096457, cited on IDS).

The teachings of Gombotz et al. have been discussed supra.

Gombotz et al. did not teach adding magnesium ions or trehalose sugar to the solution of IgM. However, the additions of magnesium ions and trehalose were well-known in the art at the time of the invention was made for stabilizing antibodies for storing purposes as evidenced by Arvinte et al. (see entire document).

In particular, Arvinte et al. taught that the addition of magnesium ions, a polyvalent action, in the form of $MgCl_2$ in an aqueous solution was preferred for pharmaceutical preparation of antibodies in high concentrations (see, e.g., pages 3-4 and 9) wherein the concentration of the magnesium ions is between 1mM to 1000mM (see page 23).

Furthermore, Arvinte et al. taught that the addition of a sugar such as trehalose, sucrose and orbital as suitable additives for pharmaceutical preparation of antibodies in high concentrations was well-known to one of ordinary skill in the art at the time of the invention was made (see page 11). In addition to the sugars, Arvinte also taught salt-forming counterions such as sodium (page 11). Though Arvinte did not explicitly teach magnesium, one of ordinary skill in the art would have readily recognized that magnesium in the form of $MgCl_2$ is also a salt-forming counterions Mg^{2+} in aqueous solutions.

It is noted that claims 12 and 34 recite product-by-process limitations wherein said pharmaceutical formulation or solution is produced by the recited processes. However such processes do not distinguish from the antibody solution in the art. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Nevertheless, Arvinte

also taught the aqueous solution of antibodies can be obtained by freezing or lyophilizing the solution (see page 2).

Given the teachings of Gombotz and Arvinte, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to add magnesium ions in the form of $MgCl_2$ and sugars such as trehalose, sucrose and sorbitol in a pharmaceutical preparation of highly concentrated IgM because magnesium ions in the form of $MgCl_2$ and sugars such as trehalose, sucrose and sorbitol were well-known additives for stabilization of the antibodies in the solution as evidenced by Arvinte.

Furthermore, given that both Gombotz and Arvinte had recognized the need to stabilize antibodies in solution for therapeutic uses (see Introduction of Gombotz and Background of the Invention of Arvinte), one of ordinary skill in the art would have been motivated to add $MgCl_2$ and sugars such as trehalose, sucrose and sorbitol as suitable stabilizers in a solution of IgM as taught by Gombotz for the purpose of achieving stabilized IgM in the pharmaceutical preparations.

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
January 6, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
January 21, 2009